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K043216

7 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

1. Identification of Submitter:

Submitter:	Confirma, Inc.
Address:	821 Kirkland Avenue
	Kirkland, WA 98033
Phone:	425-576-1226
Fax:	425-576-9295
Contact:	Patricia A. Milbank
Title:	Regulatory Consultant
Phone:	425-894-9733
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Date Prepared:	November 19, 2004

2. Identification of Product:

Trade Name:	CADstream™ Version 4.0
Common Name:	Picture Archiving and Communications System
Classification Name:	Image Processing System (LLZ) 21 CFR 892.2050
Manufacturer:	Confirma, Inc.
	821 Kirkland Avenue
	Kirkland, WA 98033

3. Marketed Devices

The multi-modality review workstation provided in CADstream Version 4.0 is substantially equivalent to the devices listed below:

Model:	Seno Advantage
Manufacturer:	GE Medical Systems
510 (k) Number:	K033400
Model:	Sectra IDS5 Radiology Workstation
Manufacturer:	Sectra-Imtec Ab
510 (k) Number:	K033712, K040376

4. Device Description:

The CADstream device relies on the assumption that pixels having similar MR signal intensities represent similar tissues. The CADstream software simultaneously analyzes the pixel signal intensities from multiple MR sequences and applies multivariate pattern recognition methods to perform tissue segmentation and classification. CADstream is designed to analyze dynamic breast MRI studies.

The CADstream system consists of proprietary software developed by Confirma installed on off-the-shelf personal hardware. The CADstream System consists of the following key components:

- A PC Server: a desk-side or rack-mount PC capable of running the Server software, Client User Interface software, and Study Viewer software
- Server software: performs CADstream analysis and processing
- Client User Interface software: an administrative web page hosted on the Server
- Study Viewer software (CADalyst): an Image Viewer component, optimized for viewing breast MR studies processed by CADstream
- Archive System: a PC with a combination CD/DVD burner and printer

To initiate CADstream analysis and processing, images are acquired and pushed to the CADstream system from the MR scanner. CADstream is configured to automatically process the images and create additional series. In this configuration, CADstream forwards the processed and original images to the existing softcopy reading station.

CADstream Version 4.0 includes the following software features:

- CADstream™, which allows the user to select a study to view, define settings for CADstream processes, process and export CADstream results, and perform administrative tasks.
- CADalyst™ (the study viewer), which allows the user to view CADstream results, interact with the volumes, curves, and AngioMap overlays, and print and save a CADstream Portfolio. This component can be accessed from a standalone CADstream workstation, a remote computer connected to the same network as the CADstream server, such as a PACS, or a PC.
- CADalyst includes multi-modality viewing capabilities, allowing the user to view ultrasound and digitized mammographic images. The ultrasound and digitized mammographic images displayed on the CADalyst remote image viewer must not be used for primary diagnostic interpretation.

- SureLoc™ is a guidance tool that assists the user in calculating target coordinates for biopsy, wire localization, or other interventional procedures.
- DICOM query/retrieve and print, which allows retrieval of DICOM data from any DICOM-compliant device that is configured for CADstream query and retrieval.

5. Indications for Use

CADstream is a computer aided detection (CAD) system intended for use in analyzing magnetic resonance imaging (MRI) studies. CADstream automatically registers serial patient image acquisitions (in 2D or 3D) to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps, referred to as angiogenesis maps), and provides quantitative measurements of morphological features of the segmented tissues. CADstream performs other user-defined post-processing functions (image subtractions, multiplanar and oblique reformats, maximum intensity projections, image averaging, removal of cardiac artifact).

CADstream also can be used to provide accurate and reproducible measurements of the segmented tissue volumes (volumes of interest (VOI)). These measurements include longest diameter, longest in-plane diameters, volume measurement (reported in cc), ratio of breast volume to VOI, distance of VOI to anatomical landmarks, and 3D renderings of the VOI.

The system includes an optional remote image viewer (CADalyst™), optimized for viewing breast MR studies processed by CADstream. CADalyst also displays and telecommunicates images from a number of other medical modalities, including ultrasound and digitized mammographic images, processed data from FDA-cleared third party image processing systems, and FDA-approved systems for computer-aided detection and advanced image processing. The ultrasound and digitized mammographic images displayed on the CADalyst remote image viewer must not be used for primary diagnostic interpretation.

CADstream™ includes software to support the use of interventional breast coils and MR stereotactic localization devices to perform MR-guided breast interventional procedures (SureLoc™). Using information from MR images regarding the coordinates of a user-specified region of interest, and fiducial coordinates, the software provides an automatic calculation of the location and depth of the targeted region of interest, such as a lesion or suspected lesion.

CADstream also includes the option to add annotations based on the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS®) Breast Imaging Atlas.

When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. Patient management decisions should not be made based solely on the results of CADstream analysis.

6. Comparison with Predicate Devices

The CADalyst multi-modality review workstation provided with CADstream Version 4.0 is substantially equivalent to the following image processing systems used by radiologists:

Seno Advantage Workstation
Manufacturer: GE Medical Systems
510 (k) Number: K033400

Sectra IDS5 Radiology Workstation
Manufacturer: Sectra-Imtec Ab
510 (k) Number: K033712, K040376

Each of these workstations allows easy selection, review, processing, archive, printing and media interchange of multi-modality images from a variety of diagnostic imaging systems.

7. Conclusions

CADstream Version 4.0, with the remote CADalyst multi-modality review workstation, provides additional features to further integrate radiology department workflow. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. The CADstream system provides images comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2005

Ms. Patricia A. Milbank
Regulatory Consultant
Confirma, Inc.
821 Kirkland Avenue, Suite 100
KIRKLAND WA 98033

Re: K043216
Trade/Device Name: CADstream™ Version 4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 19, 2004
Received: November 22, 2004

Dear Ms. Milbank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K043216

6 Indication(s) for Use Statement

510(k) Number: To be assigned by FDA

Device Name: CADstream™ Version 4.0

Indications for Use:

CADstream is a computer aided detection (CAD) system intended for use in analyzing magnetic resonance imaging (MRI) studies. CADstream automatically registers serial patient image acquisitions (in 2D or 3D) to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps, referred to as angiogenesis maps), and provides quantitative measurements of morphological features of the segmented tissues. CADstream performs other user-defined post-processing functions (image subtractions, multiplanar and oblique reformats, maximum intensity projections, image averaging, removal of cardiac artifact).

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043216